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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/331,376	06/18/1999	OYSTEIN FODSTAD	7885.65USWO	1579

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MERCHANT & GOULD PC  
P.O. BOX 2903  
MINNEAPOLIS, MN 55402-0903

[REDACTED] EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
1642	25

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

*part of file - see*

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/331,376	FODSTAD ET AL.
	Examiner	Art Unit
	MINH-TAM DAVIS	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 24 December 2002.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-4,6-11 and 13-17 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-4,6-11 and 13-17 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on **12/24/02** has been entered.

The following are the remaining rejections.

Accordingly, claims 1-4, 6-11, 13-17 are examined in the instant application.

### **REJECTION UNDER 35 USC 103**

Claims 1-4, 6-11, 13-17 remain rejected under 35 USC 103 as being obvious over Hajek et al, in view of Fodstad et al and O'briant et al, for reasons already of record in paper No:22.

Applicant argues that Hajek et al teach away from visualization in suspension, suggesting that it is inferior to visualizing cells smeared on a slide (column 3, lines 61-64). Applicant asserts that Hajek et al further teach that clumping can occur in suspension, which is incompatible with the presently claimed method, due to steric hindrance and quenching problem of clumping. Applicant argues that nothing in Hajek et al would suggest one of skill in the art to visualize cells in suspension.

Concerning Hajek et al teaching that clumping occurs at only high concentration, Applicant asserts that as the number of different particles with different associated antigens increase, the amount of clumping would be expected to increase. Applicant asserts that it is a surprise that the claimed method could be performed without clumping.

Applicant asserts that Fodstad et al teach conditions for detecting specific target cells, using a single paramagnetic particle associated with a single antibody species. Fodstad et al do not teach that clumping can be avoided when using multiple particles as required by the present claims.

Applicant asserts that O'briant et al do not cure the deficiencies of the Hajek and Fodstad patents. Applicant asserts that O'briant et al do not teach how one would avoid the clumping problem.

Applicant's arguments in paper No:24 have been considered but are found not to be persuasive, because of the following reasons:

It is not an expected result that cell suspension could be visualized under microscope as taught by Hajek et al and Fodstad et, without the problems associated with cell clumping when using the method taught by Hajek et al, i.e., using different particles with different associated antigens, because under normal cell concentration range of 4-11,000 cells per microliter, cell clumping does not occur when using different particles with different associated antigens, as taught by Hajek et al (column 12, lines 37-49).

Further, although Hajek et al teach that morphologic evaluation of cells taught by one prior art procedure is limited when the cells are evaluated in a suspension, and not evaluated on slides (column 3, lines 61-64), this statement does not necessarily indicate that Hajek et al teach that visualization in suspension is inferior to visualizing cells smeared on a slide, because the conditions taught by the prior art procedure cited by Hajek et al are not known, and because depending on different conditions, e.g. different cell concentrations, cell clumping might or might not occur, as taught by Hajek et al, who teach that with cell counts of 40-50,000 cells or greater per microliter, cell clumping occurs and that under normal cell concentration range of 4-11,000 cells per microliter, cell clumping does not occur when using different particles with different associated antigens (column 12, lines 37-49).

Moreover, Fodstad et al do not just teach conditions for detecting specific target cells, using a single paramagnetic particle associated with a single antibody species. Fodstad et al also teach incubation of the cell suspension with a mild detergent and/or second set of antibodies will dramatically increase the specificity of the method (page 4, last five lines of the first paragraph). The number of particles taught by Fodstad et al is within the range of the claimed particles, i.e. 2 to 6 particles.

In addition, Fodstad et al recognize that aggregation of cells may cause problems (page 5, last sentence of the paragraph before last). Fodstad et al further teach that using cell suspension in the microscope is rapid and simple, and can be performed by any investigator with access to a conventional microscope (p.6, first paragraph).

Thus in view of the fact that 1) Hajek et al and Fodstad et al teach detection and identification of cells in suspension using microscope, 2) using cell suspension in the microscope is rapid and simple, and can be performed by any investigator with access to a conventional microscope, as taught by Fodstad et al, 3) the art recognizes that aggregation of cells may cause a problem, as taught by Fodstad et al, and further in view of the fact that aggregation of cells does not occur under normal cell concentration range of 4-11,000 cells per microliter, when using different particles with different associated antigens, as taught by Hajek et al, it would have been obvious to use different particles with different associated antigens, as taught by Hajek et al and Fodstad et al, for detection of cells in suspension under microscope, wherein under normal cell concentration of 4-11,000 cells per microliter, one would not have expected clumping problem.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

February 17, 2003

  
ANTHONY C. CAPRA  
INTERIM PATENT EXAMINER  
TELEPHONE NUMBER